REMARKS

Claims 80-106 are pending in this application. Claims 82, 87, 94, 96, 103 and 105 have been canceled, without admission and without prejudice to Applicants' right to pursue the subject matter in this or other (*e.g.*, continuing) applications. Claims 80, 83, 89, 95, 98 and 104 have been amended, *supra*. Specifically, independent claims 80, 94 and 103 have been amended to specify dosage forms comprising an oxymorphone *salt*, rather than "oxymorphone or a salt thereof." In addition, these claims have been amended to incorporate limitations of the canceled dependent claims. In particular, the amended dependent claims now specify that the dosage forms additionally contain an alkylcellulose, and provide a therapeutic effect for about 12 hours or more. Dependent claims 83, 95 and 104 have been amended to more particularly specify that the alkylcellulose in these dosage forms is ethylcellulose. The amendments to the claims are all made without admission, and without prejudice to Applicants' right to pursue any surrendered subject matter in this or other (*e.g.*, continuing) applications. As explained above, then amendments do not introduce new matter to the application. Accordingly, their entry and consideration are respectfully requested.

Applicants note, with appreciation, that the previous rejections of the pending claims for obviousness (35 U.S.C. § 103(a)) and obviousness-type double patenting have been withdrawn. However, the Examiner has issued new rejections of the pending claims over newly cited "prior art". Each of these rejections is discussed in turn below.

A. The Rejection For Obviousness Over Robson

Claims 80-84, 87-91, 93-100 and 102-106 have been rejected as obvious over U.S. Patent No. 4,126,684 to Robson *et al.* ("Robson"), considered either alone or as evidenced by U.S. Patent No. 3,758,680 to Henderson *et al.* ("Henderson"). According to the Office Action, "Robson teaches tablet dosage forms containing a PEG 6000 as a hydrophilic polymer, lactose as a diluent, and corn starch, talcum powder and magnesium sterate as binders." *Office Action at 3*. Robson is also said to describe preparing these formulations by pressing powders through a screen with openings of 0.6 mm, which is said to provide granules within the size ranges

specified by the dependent claims, as well as the preparation of a "matrix-tablet" containing an "aqueous gelling matrix." *Id.* Finally, the active ingredient oxymorphone is said to be "specifically suggested as a drug for use in these dosage forms." *Id. at 3-4.*

The Examiner apparently acknowledges that Robson does not specifically teach a composition having the sustained release properties recited in the claims (*e.g.*, providing a therapeutic effect for 12 hours or more). However, it is asserted, in the Office Action, that "a composition having the same components is expected to have the same properties." *Office Action at 4.* The Office Action cites to Henderson "as evidence supporting the position that the compositions of Robson do indeed have the claimed [sustained release] properties." *Id.* In particular, Henderson is said to teach "that ethyle cellulose causes sustained release in pellets and granules when blended with active drugs." *Id.*

Applicants respectfully traverse this rejection, and request that it be withdrawn. At the outset, Applicants note that the examples the Examiner cites to in Robson describe formulations of certain, specific drugs: levorphanol tartrate (Example 1) and codeine phosphate (Example 2). Robson may identify oxymorphone as one of over thirty "addicting agents" from which a sustained release formulation may be prepared. However, it does not describe a single sustained-release formulation of any oxymorphone salt, as specified in the amended claims. Moreover, the formulations in these examples do not contain an alkylcellulose.

There is no suggestion or motivation to modify the specific formulations taught by Robson, *e.g.*, by preparing the formulation with an oxymorphone salt. Also, such a composition would not be reasonably expected to have the sustained release properties specified by the amended claims. Contrary to what the Office Action states, Henderson provides no evidence that the compositions in Robson do, or might be expected to have, such sustained-release properties. To the contrary, Henderson only describes specific formulations of the drug sulfonamide, and states that "the 3 and 5 percent ethylcellulose formulations [in that Example] give a sustained release of sulfonamide starting at 36 or 48 hours respectively." Henderson at col. 7, lines 48-50. Henderson then states that "[t]he 7 percent ethylcellulose formulation did

give sustained release but did not achieve satisfactory sulfonamide blood concentrations." *Id.* at col. 7, lines 51-53. Hence, Henderson actually teaches that ethylcellulose formulations will not necessarily "provide a therapeutic effect for about 12 hours or more," and therefore teaches away from the invention as claimed.

B. The Rejection For Obviousness Over Robson and Mughal

Claims 85, 92 and 101 have been rejected as obvious over Robson in further view of U.S. Patent No. 4,524, 060 to Mughal *et al.* ("Mughal"). Those dependent claims additionally specify that the claimed dosage form is in the form of a capsule. Mughal is said to teach "that it is useful to provide such compositions as sustained release capsules for oral delivery." *Office Action at 4*; citing *Mughal (Abstract)*. However, Mughal does not overcome the above described deficiencies of Robson. In particular, Mughal only describes formulations of the drug indoramin, and does not teach or suggests compositions of oxymorphone salt. The rejection of these claims for obviousness therefore should also be withdrawn.

CONCLUSION

Applicants respectfully submit that the foregoing remarks overcome and/or obviate each basis for rejection set forth in the Office Action. The pending claims as amended are all believed to be in immediate condition for allowance. Accordingly, the withdrawal of all objections and rejections is respectfully requested. An allowance is earnestly sought.

Respectfully submitted,

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